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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,061	07/31/2003	Robert E. Richard	02-321	9972

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EXAMINER	
SIMMONS, CHRIS E	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,061	RICHARD ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-20 and 22-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-20 and 22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/10/2009 has been entered.

Applicants' arguments, filed 07/10/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Applicant's arguments, see pages 6 and 7, filed 07/10/2009, with respect to the rejections of the claims under USC Section 103(a) SCHWARZ (US 2003/0236514) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of graft copolymers being well known for use in implantable or insertable medical devices.

Objections

Applicant is advised that should claim 22 be found allowable, claim 25 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11-20, and 22-26 are rejected under 35 USC 103(a) as being unpatentable over Pinchuk et al. (US 2002/0107330) in view of RUCKENSTEIN et al. (WO 00/59968).

'330 discloses an intravascular or intervascular medical device (e.g., a stent; ¶ 15) comprising a therapeutic agent-releasing biocompatible block polymer, said polymer is a copolymer that may be linear triblock (¶ 28) or branched (¶ 32), said copolymer comprising a therapeutic agent (e.g., heparin; ¶ 62), elastomeric blocks (e.g., polyolefins; ¶ 33 and claim 42) and thermoplastic blocks (e.g., vinyl aromatic blocks or methacrylate blocks (¶ 8 and claim 44), especially poly(methyl methacrylate) (¶ 8, claim 45)) (See abstract, ¶ 177-178). The device may be coated with the polymeric material (¶ 11). Preferred sites for implantation or insertion of the medical device are the coronary vasculature, peripheral vasculature, esophagus, trachea, colon, gastrointestinal tract, biliary tract, urinary tract, prostate and brain (¶ 13). The copolymer may comprise of units that have glass transitional temperatures above and below ambient temperature and, therefore meets the required limitations in instant claims 22-25. '330 does not expressly disclose graft copolymers.

'968 discloses that great attention has been paid to graft copolymers, because of their unique molecular architecture, particular morphology, and increased number of

applications. The incorporation of functional groups into the surface of polymer materials or into polymeric chains can greatly improve their properties. For instance, the direct introduction of new functionalities onto a polymer surface or the surface modification by grafting can change the surface hydrophilicity, hydrophobicity, biocompatibility, and adhesion. The direct synthesis of well-defined graft copolymers with functional groups can control not only the properties of the surface, but also the molecular parameters, architecture, and composition of the polymer. The copolymer compositions can be used as to deliver drugs. The reference does not expressly teach an implantable or insertable medical device.

At the time of the invention it would have been obvious to a person of ordinary skill in the art to create an insertable or implantable medical device (e.g., stent) containing copolymers as described in the primary reference by grafting the copolymers as described in the secondary reference. The suggestion/motivation for doing so would have been to control not only the properties of the surface, but also the molecular parameters, architecture, and composition of the polymer as explained in the secondary reference.

Claims 8 and 27 are rejected under 35 USC 103(a) as being unpatentable over Pinchuk et al. (US 2002/0107330 A1) in combination with RUCKENSTEIN et al. (WO 00/59968) taken in view of WILLIAMS (US 6,514,515).

The disclosures for Pinchuk et al. and RUCKENSTEIN et al. and the rationale for the combination are outlined above. However, they do not expressly disclose an elongation at break of at least 25% at ambient temperature.

WILLIAMS relates to bioabsorbable biocompatible polymers which provide a good match between their mechanical properties and those of certain tissue structures. The bioabsorbable biocompatible polymers can be prepared with tensile strengths, elongation to breaks, and/or tensile modulus (Young's modulus) values of the tissues of the cardiovascular, gastrointestinal, kidney and genitourinary, musculoskeletal, and nervous systems, as well as those of the oral, dental, periodontal, and skin tissues. (Abstract). FIG. 1, plots the tensile strength and elongation to break values for representative FDA approved bioabsorbable biocompatible polymers against these values for different tissue structures. It displays a significant mismatch between the mechanical properties of these polymers and the different tissue structures. In particular, it is apparent that the existing bioabsorbable biocompatible polymers are stiff, inelastic materials, with elongations to break of around 25%, yet many tissues are much more flexible, elastic, and have longer elongation to break values (above 25%). Accordingly, the biomaterial products used did not exhibit the same multi-axial physical and mechanical properties of native tissues (1st full paragraph of column 2). To remedy the problem, the inventors preferably developed polymeric devices with elongation at break above 25%. The compositions described have an advantageous ability to be sterilized by radiation (1st paragraph in column 8). The reference does not expressly teach acrylic graft copolymers.

At the time of the invention it would have been obvious to a person of ordinary skill in the art to create an insertable or implantable medical device containing graft copolymers as disclosed above having an elongation of break of at least 25% as described by WILLIAMS. The suggestion for doing so would have been to increase the flexibility and elasticity of a biomedical device to more closely match the native tissue in which the device is inserted/implanted.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11-20, and 22-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7,357,940. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent does not claim the graft

copolymer as being block copolymers, whereas the instant claims are directed to graft copolymers that are block copolymers. However, one of ordinary skill in the art would find it obvious to make the graft copolymers as block graft copolymers since the patent defines the graft copolymers as block graft copolymers in its specification at column 5, lines 7-11.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612